

Will H. Cai +852 3758 1210 wcai@cooley.com

#### December 18, 2020

#### VIA EDGAR

U.S. Securities and Exchange Commission Office of Life Sciences Division of Corporation Finance 100 F Street, N.E. Mail Stop 4546 Washington, D.C. 20549

Attn: Mr. Franklin Wyman Ms. Sasha Parikh Ms. Abby Adams Ms. Christine Westbrook

#### Re: Gracell Biotechnologies Inc. Registration Statement on Form F-1 and Response to the Staff's Comment Letter Dated December 11, 2020 CIK No. 0001826492

Ladies and Gentlemen:

On behalf of our client, Gracell Biotechnologies Inc. (the "*Company*"), we are responding to the comments (the "*Comments*") of the staff (the "*Staff*") of the Securities and Exchange Commission (the "*Commission*") contained in its letter dated December 11, 2020 (the "*Comment Letter*"). Concurrently with the submission of this letter, the Company is publicly filing its registration statement on Form F-1 (the "*Registration Statement*") and certain exhibits via EDGAR. To facilitate the Staff's review, we are also delivering four clean copies of the Registration Statement and four copies marked to show all changes to the draft registration statement confidentially submitted to the Commission on November 24, 2020.

Set forth below are the Company's responses to the Comments. The numbering of the paragraphs below corresponds to the numbering of the Comments, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Registration Statement. Capitalized terms used but not defined herein are used herein as defined in the Registration Statement.

The Company respectfully advises the Staff that it intends to file an amendment to the Registration Statement on Form F-1 containing the estimated price range and offering size on or about January 4, 2021 and commence roadshow activities thereafter. The Company would appreciate the Staff's continued assistance to help the Company meet this timeline.

#### Prospectus Summary, page 1

1. Please revise the risk factors on pages 76 and 93 and the related disclosure in the Summary to clarify if the PRC could prevent you from seeking foreign approval and commercialization of any of your product candidates. Revise also to disclose in the Summary any research and development activities your wholly foreign-owned enterprise Gracell Bioscience is engaged in, whether any research and development at any of the VIEs may be attributable to Gracell Bioscience, and the basis to support your determination that the prohibition under the Negative List does not apply to your operations. Please also revise to define the term "WFOE" at its first use.

Cooley科律 December 18, 2020 Page 2

Additionally, please expand your disclosure to address the following risks, as applicable:

- intellectual property rights and protections may be insufficient to protect your intellectual property in China;
- the increased global focus on environmental and social issues and China's potential adoption of more stringent standards in these areas may adversely impact your operations;
- potential adverse tax-consequences to shareholders if you are determined to be a resident enterprise for PRC tax purposes; and
- Chinese governmental authorities have significant discretion that can be used to influence how you conduct your business and operations.

# Refer to the Division of Corporation Finance Disclosure Guidance Topic No. 10 "Disclosure Considerations for China-Based Issuers."

#### Response to Comment 1:

In response to the Staff's comment, the Company respectfully submits the following:

With respect to the risk factors regarding Negative List, the Company has revised the disclosure on pages 9 and 75 of the Registration Statement as requested.

Cooley科律 December 18, 2020 Page 3

- With respect to the research and developments activities conducted by the WFOE, the Company has revised the disclosure on pages 9, 10 and 120 of the Registration Statement as requested.
- With respect to the intellectual property rights and protections, the Company has revised the disclosure on page 63 of the Registration Statement as requested.
- With respect to the increased global focus on environmental and social issues, the Company has revised page 51 of the Registration Statement as requested.
- With respect to the potential adverse tax-consequences to the shareholders if the Company is determined to be a resident enterprise for PRC tax purposes, the Company has revised the risk factor disclosure on page 82 of the Registration Statement as requested.
- With respect to the influence of the discretion of Chinese governmental authorities on Company's business and operations, the Company respectfully submits that it has disclosed on pages 77 through 92 of the Registration Statement risks related to doing business in China, including restrictions on transfer of scientific data outside of China (page 79), obtaining offshore investments (pages 84 and 85).

## Overview, page 1

2. We note your response to comment 2 and reissue with respect to references to potentially enhanced safety and efficacy and disclosure that implies the safety profile of your product candidates has been established.

Response to Comment 2:

In response to the Staff's comment, the Company has revised the disclosure on pages 1, 127, 146, 159, 160, 163, 166, 167 of the Registration Statement as requested.

3. We note your response to comment 4 and reissue with respect to references to product candidates as potentially "first-in-class."



December 18, 2020 Page 4

# Response to Comment 3:

In response to the Staff's comment, the Company has removed the references to each product candidate being potentially first-in-class in its own category if approved, from pages 5 and 148 of the Registration Statement. However, the Company respectfully submits to the Staff that, to its knowledge, all dual antigen targeting CAR constructs that are being developed (except for GC012F) are targeting two identical antigens and therefore GC012F is **first-in-class in its design** by simultaneously targeting two different antigens, BCMA and CD19.

4. We note your response to comment 22 indicating that you do not have access to data from the Phase 1 investigator-initiated trials until the data is published. Please revise your disclosure in the Summary to highlight this limitation. It should be clear from your disclosure throughout your prospectus that you do not have access to data while the trials are being conducted and are dependent on receiving published data. Revise any references to partnering on these studies to explain your involvement. Similarly, revise your pipeline table presentation to convey the limited scope of your involvement and that you do not have access to data from the investigator-initiated studies until the data is published. Lastly, please highlight the risks associated with your lack of access to the data under an appropriate heading in the Risk Factors section.

# Response to Comment 4:

In response to the Staff's comment, the Company has revised and made additional disclosure on pages 5, 148, 163, 165, 167 through 172 of the Registration Statement as requested. Additionally, the Company has revised and added risk factors on pages 8, 28 and 29 of the Registration Statement as requested.

#### **Risk Factors, page 18**

5. To the extent any risk factor included in your prospectus could involve any registrant or any offering, revise this section to relocate all such risk factors at the end of this section under the caption "General Risk Factors." Refer to Item 3 of form F-1 and 105(a) of Regulation S-K and Section II.D. of Release No. 33-10825, "Modernization of Regulation S-K Items 101, 103, and 105" (Oct. 8, 2020).



December 18, 2020 Page 5

#### Response to Comment 5:

In response to the Staff's comment, the Company has moved the general risk factors to pages 102 through 107 of the Registration Statement.

#### Dilution, page 115

6. Please provide the information added to the Capitalization table in response to prior comment 12 to the corresponding section of the Dilution table.

#### Response to Comment 6:

In response to the Staff's comment, the Company has revised the disclosure on page 116 of the Registration Statement to include the impact of share-based compensation expense for options to be recorded upon the completion of this offering.

#### Management's Discussion and Analysis of Financial Condition and Results of Operations

#### **Results of Operations**

#### Comparison of Nine Months Ended September 30, 2019 and 2020

#### **Operating Expenses**

#### Administrative Expenses, page 130

7. Please tell us why "research and development activities" are included in your discussion regarding changes in your administrative expenses or revise.

#### Response to Comment 7:

In response to the Staff's comment, the Company respectfully submits that the increased research and development ("**R&D**") activities affected the administrative expenses in both directions. On the one hand, increased R&D activities required more daily administrative supporting work which resulted in increased personnel expenses and labor outsourcing costs that ultimately contributed to an increase in administrative expenses. On the other hand, given that rental and depreciation expenses are allocated between R&D and administrative expenses in proportion to the working space for R&D and administrative activities, increased R&D activities required more working space and thus resulted in a reduced allocation of rental expenses and depreciation expenses to administrative expenses.

# **Cooley**科律

December 18, 2020 Page 6

The Company has revised the disclosure on page 131 of the Registration Statement to clarify the impact of R&D activities on administrative expenses.

#### Loan Agreements, page 134

8. We note your response to comment 13 and do not agree with your conclusion that your loan agreements are not material contracts required to be filed as exhibits. In this regard, we note that you have a history of losses, will continue to incur research and development expenses and may not be profitable in the near future. Please file your loan agreements with Bank of China, China Construction Bank and China Merchants Bank as exhibits to your registration statement.

#### Response to Comment 8:

In response to the Staff's comment, the Company has filed the loan agreements as Exhibits 10.15 through 10.20 to the Registration Statement as requested.

#### **Critical Accounting Policies, Judgments and Estimates**

#### Research and Development Expenses, page 140

9. Your revised disclosure presents research and development expenses for each of your significant product candidates and separately by the major components of your research and development expenses. Please clarify how these two tables are integrated or revise to incorporate both tables into one table that reconciles to total research and development expense on the Consolidated Statements of Comprehensive Loss.

#### Response to Comment 9:

In response to the Staff's comment, the Company has revised and made additional disclosure on pages 142 and 143 of the Registration Statement to reconcile these two tables.

#### **Share-Based Compensation, page 143**

10. Once you have an estimated offering price or range, please explain to us how you determined the fair value of the common stock underlying your equity issuances and the reasons for any differences between the recent valuations of your common stock leading up to the IPO and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation. Please discuss with the staff how to submit your response.

# **Cooley**科律

December 18, 2020 Page 7

# Response to Comment 10:

In response to the Staff's comment, the Company has submitted a separate letter explaining how the Company determined the estimated fair value of its ordinary shares and the reasons for any differences between the recent valuation of the Company's ordinary shares leading up to the Company's initial public offering and the estimated offering prices. The Company respectfully requests, pursuant to 17 C.F.R. §200.83, that certain portions of that letter be maintained in confidence, not be made part of any public record and not be disclosed to any person, due to the commercially sensitive nature of information contained in that letter.

#### Business, page 145

11. We note your response to comment 20 and reissue the comment to the extent you have not revised the disclosure to define Grade 1 and higher adverse events as discussed in your response.

#### Response to Comment 11:

In response to the Staff's comment, the Company has revised page 12 of the Registration Statement.

12. We reissue comment 22 in part. To the extent you do not have access to study data for the studies you describe in your response, revise this section to explain your limited access. Tell us how you have access to the data you do have, and whether you have any agreement regarding the sharing of data or information. Tell us when, if ever, you expect to obtain access to full information on the studies, including not only results but the underlying data collected. For example, tell us whether you will obtain access to the information prior to submitting your IND applications to the FDA. In addition, revise to state what actions you have taken in the studies for which you do not have access to the data. For example, you continue to state "our trial" (page 163) and "we observed" (page 164) with respect to the GC012F study, and "we administered all patients with a single infusion" in the GC027 study, on page 167. To be clear that you are not conducting these studies, revise throughout this section to avoid the passive voice and state who is taking the actions you describe.

#### Response to Comment 12:

In response to the Staff's comment and comment 4 above, the Company has revised and made additional disclosure on pages 5, 148, 163, 165 through 172 of the Registration Statement as requested. Additionally, the Company has revised and added risk factors on pages 8, 28 and 29 of the Registration Statement as requested.

#### **Intellectual Property, page 173**

13. We note your response to comment 23 and do not agree with your conclusion that your license agreement with ProMab is an ordinary course contract not required to be filed as an exhibit to your registration statement. Further, we note your disclosure on page 64 that "[i]f we fail to comply with the obligations . . . our licensors may have the right to terminate the license," and, if terminated, you "may not be able to develop, manufacture, market or sell the product covered by our agreements," which "could materially adversely affect the value of the product candidates being developed under any such agreement." Please file your license agreement with ProMab as an exhibit to your registration statement.



December 18, 2020 Page 8

## Response to Comment 13:

In response to the Staff's comment, the Company has filed the exclusive license agreement between Unitex Capital, Ltd. ("*Unitex*") and Promab Biotechnologies, Inc. ("*ProMab*"), and the amended and restated No. 1 to exclusive license agreement with sublicensing terms among Gracell Biotechnologies (Shanghai) Co., Ltd., Unitex and ProMab as Exhibits 10.21 and 10.22 to the Registration Statement as requested.

# 14. We reissue comment 24 in part. Revise to describe the scope of patent protection you seek with respect to your patent applications described in this section.

#### Response to Comment 14:

In response to the Staff' comment, the Company has revised page 176 of the Registration Statement as requested.

#### Taxation, page 245

15. We reissue comment 28 in part. Revise the discussion of PRC tax consequences to provide an opinion of counsel as to the material PRC tax consequences of the ownership of your ordinary shares represented by American Depositary Shares.

# Response to Comment 15:

In response to the Staff's comment, the Company has revised page 240 of the Registration Statement as requested.

\* \* \* \*

Please direct any questions or comments concerning the Registration Statement or this response letter to either the undersigned at +852-3758-1210 or via e-mail at wcai@cooley.com.

Very truly yours,

/s/ Will H. Cai Will H. Cai

cc: William Wei Cao, Chairman and Chief Executive Officer, Gracell Biotechnologies Inc. Yili Kevin Xie, Chief Financial Officer, Gracell Biotechnologies Inc. Alex Zhuang, Partner, PricewaterhouseCoopers Zhong Tian LLP James C. Lin, Esq., Partner, Davis Polk & Wardwell LLP Yasin Keshvargar, Esq., Partner, Davis Polk & Wardwell LLP